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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,925	06/20/2001	Seiichi Araki	MTSU-1001US	7925

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EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	10

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/806,925	Applicant(s) ARAKI ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 6/20/01 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1 - 15 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that each of the groups contain the same special technical feature of a sugar cane-derived extract. This argument is found persuasive; therefore the election/restriction requirement has been withdrawn. Claims 1 – 60 have been examined on the merits.

Drawings

The drawings are objected to because the writing is small, cut off and illegible. Correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 15, 19, 28, 34, 43 and 46 – 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composition however are rendered vague and indefinite for reciting "a preventative" because the term is not adequately defined.

The claims are further indefinite for reciting "for infection" because it is unclear what kind of infection is prevented or remedied. For example, is the composition is a remedy for both bacterial infection and viral infection?

Claims 4, 19, 34 and 49 are confusing because it is unclear what is "utilizing differences" in affinity for ion exchange.

Claims 13, 28, 43 and 58 are vague and indefinite for reciting "or lower" because it is unclear what component is lower in the ratio. For example, is the water content or ethanol content lower?

Claim 46 and its dependents are drawn to a growth promoter, however are rendered indefinite because it is unclear what type of growth is promoted. For example, does the composition promote growth of plants, fungi, viruses, bacteria, nerves, fibroblasts or animals?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1 – 3, 16 – 18, 31 – 33 and 46 – 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawai (JP 11189519 A).

Applicant claims a composition comprising a sugar cane derived extract as the active ingredient. The extract is obtained from a raw material selected from sugar cane juice, a liquid extract of sugar cane and sugar cane derived molasses via column chromatography with a fixed carrier. The fixed carrier is a synthetic adsorbent, and is eluted with a solvent selected from water, methanol, ethanol or a mixture thereof. The composition is a remedy for infection, a vaccine adjuvant, anti-endotoxin and/or growth promoter.

Kawai teaches a sugar cane extract that is obtained by treating raw sugarcane juice or molasses with column chromatography filled with synthetic adsorbent (abstract). The adsorbents are then eluted with water, methanol, ethanol or mixtures thereof (abstract).

Although Kawai does not specifically teach the extract has each of the above activities, the compositions are the same. Moreover, the activities are inherent to the composition of Kawai. Therefore, the reference anticipates the claimed subject matter.

5. Claims 1, 16, 31 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Bueno (1992).

Applicant claims a composition comprising a sugar cane derived extract as the active ingredient. The composition is a remedy for infection, a vaccine adjuvant, anti-endotoxin and/or growth promoter.

Bueno teaches methods of obtaining pharmaceuticals from sugar cane as a raw material (abstract).

Although Bueno does not specifically teach the extract has each of the above activities, the compositions are the same. Moreover, the activities are inherent to the composition of Bueno. Therefore, the reference anticipates the claimed subject matter.

6. Claims 1, 14 – 16, 29 – 31, 44 – 46 and 59 – 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Tilby (US 5374316).

Applicant claims a composition comprising a sugar cane derived extract as the active ingredient wherein the composition is in a food product or animal feed product. The composition is a remedy for infection, a vaccine adjuvant, anti-endotoxin and/or growth promoter.

Tilby teaches sugarcane extracts used in food products and animal feeds (col.2 line 60-68).

Although Tilby does not teach the extracts are remedies for infection, vaccine adjuvants, anti-endotoxin or growth promoting, the compositions are the same. Moreover, such activities are inherent to the composition of Tilby. Therefore, the reference anticipates the claimed subject matter.

7. Claims 1, 11 – 13, 16, 26 – 28, 31, 41 – 43, 46 and 56 - 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Agar et al. (US 5788812).

Applicant claims a composition comprising a sugar cane derived extract as the active ingredient. The extract is obtained by extracting bagasse with water, a hydrophilic solvent, or a mixture thereof, wherein the hydrophilic solvent is ethanol and the mixture is ethanol and water

with a ratio of 60/40 or less. The composition is a remedy for infection, a vaccine adjuvant, anti-endotoxin and/or growth promoter.

Agar et al. teaches a process for the recovery of lignin and polysaccharides from fibrous plant material (abstract, col.4 line 39-41). The process comprises extracting fibrous plant material with a solvent comprising water and ethanol (col.4 line 8-16), specifically, 60% ethanol 40% water (col.4 line 24-26, 35-50, 45-50). Agar discloses the process is carried out with any fibrous plant material to include bagasse (col.16 line 15-20).

Although Agar does not teach the extracts are remedies for infection, vaccine adjuvants, anti-endotoxin or growth promoting, the steps of obtaining the sugar cane extracts are the same. Therefore, the compositions are the same. Moreover, such activities are inherent to the composition of Agar. Therefore, the reference anticipates the claimed subject matter.

8. Claims 1 – 7, 9, 14, 16 – 22, 24, 29, 31 – 37, 39, 44, 46 – 52, 54 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Saska et al. (US 5482631).

Applicant claims a composition comprising a sugar cane derived extract as the active ingredient. The extract is obtained from a raw material selected from sugar cane juice, a liquid extract of sugar cane and sugar cane derived molasses via column chromatography with a fixed carrier. The fixed carrier is a synthetic adsorbent, and is eluted with a solvent selected from water, methanol, ethanol or a mixture thereof. The extract absorbs light at 420nm when utilizing an ion exchange resin as the fixed carrier, specifically a strongly acidic cation exchange resin in sodium or potassium form. Further, the ion exchange chromatographic treatment is carried out in a pseudo moving bed continuous separation method. The composition is a remedy for

infection, a vaccine adjuvant, anti-endotoxin and/or growth promoter. Applicant additionally claims a food comprising the composition.

Saska et al. teaches that cane molasses, a raw plant extract, can be refined into food grade sugar (col.1 line 34-40). Saska teaches methods wherein the sugar cane molasses is run through a cation exchange resin in potassium or sodium form (col.1 line 44-65). Saska further teaches preferred methods include use of the simulated moving bed method (col.4 line 8-11). An example is provided wherein feedstocks of sucrose are passed through a column and eluted with water (example 1). Saska teaches that products obtained by the disclosed method are used in baby formula (col.1 line 10-15).

Although Saska does not teach the composition as a remedy for infection, vaccine adjuvant, anti-endotoxin and/or growth promoter with an absorption at 420nm, the process for obtaining the compositions is the same. Therefore, the compositions are the same. Moreover, by obtaining the sugarcane-derived extracts of Saska, one is inherently obtaining the composition as claimed. Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 2, 4, 8, 10, 16 – 17, 19, 23, 25, 31 – 32, 34, 38, 40, 46 – 47, 49, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saska et al. (US 5482631) in view of Kaken Chem Co, LTD (JP 69023346 B).

Applicant claims a composition comprising a sugar cane derived extract as the active ingredient. The extract is obtained from a raw material selected from sugar cane juice, a liquid extract of sugar cane and sugar cane derived molasses via column chromatography with a fixed carrier wherein the extract absorbs light at 420nm when utilizing an ion exchange resin as the fixed carrier. The extract is further treated with electrodialysis to decrease salt. The composition is a remedy for infection, a vaccine adjuvant, anti-endotoxin and/or growth promoter.

Saska et al. teaches cane molasses, a raw plant extract, can be refined into food grade sugar (col.1 line 34-40). Saska teaches methods wherein the sugar cane molasses is run through an ion exchange resin, followed by demineralization, or removal of salt (col.1 line 44-65).

Saska does not teach the process wherein the ion exchange resin is a gel resin. However, at the time of the invention, it would have been obvious to one of ordinary sill in the art to do so

because gel ion exchange resins were commonly used in the art at the time the invention was made. Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to use a gel resin in the method of Saska with a reasonable expectation of success for obtaining a sugarcane-derived extract.

Saska does not teach the process wherein demineralization is accomplished by electrodialysis. However, at the time of the invention, one of ordinary skill in the art would have been motivated to do so because it was a well-known process used in the art at the time the invention was made. In support, Kaken teaches a process for extracting sugarcane wherein the extract is purified by ion exchange and dialysis (abstract). Kaken further teaches that such sugarcane extracts are anti-tumor (abstract).

Although the above references do not specifically teach the composition as a remedy for infection, vaccine adjuvant, anti-endotoxin and/or growth promoter with an absorption at 420nm, the processes for obtaining the compositions are the same. Therefore, the compositions are the same. Further, Kaken does teach that such sugarcane extracts are anti-tumor. Moreover, by obtaining the sugarcane-derived extracts of Saska and Kaken, one is inherently obtaining the composition as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis
December 12, 2001

LEON B. LANKFORD, JR.
PRIMARY EXAMINER